PERKINS COIE LLP
DAVID T. BIDERMAN (No. 101577)
dbiderman@perkinscoie.com
1888 Century Park E., Suite 1700
Los Angeles, CA 90067-1721
Telephone: 310.788.9900
Facsimile: 310.843.1284

CHARLES C. SIPOS (*pro hac vice*)
csipos@perkinscoie.com
1201 Third Avenue, Suite 4900
Seattle, WA 98101-3099
Telephone: 206.359.8000
Facsimile: 206.359.9000

JOSHUA A. REITEN (No. 238985)
jreiten@perkinscoie.com
Four Embarcadero Center, Suite 2400
San Francisco, CA 94111-4131
Telephone: 415.344.7000
Facsimile: 415.344.7050

Attorneys for Defendants GENERAL MILLS, INC. and GENERAL MILLS SALES, INC.

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

TROY BACKUS, on behalf of himself and all others similarly situated,

Plaintiff,

v.

GENERAL MILLS, INC. and GENERAL MILLS SALES, INC.,

Defendants.

Case No. 15-cv-01964 TEH

DEFENDANTS' NOTICE OF MOTION AND MOTION TO DISMISS OR IN THE ALTERNATIVE STAY BASED ON PRIMARY JURISDICTION; MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT

Date: August 17, 2015
Time: 10:00 a.m.
Place: Courtroom 2, 17th Floor
Judge: Hon. Thelton E. Henderson

TABLE OF CONTENTS

PAGE

TABLE OF AUTHORITIES

PAGE

CASES

STATUTES/REGULATIONS

NOTICE OF MOTION AND MOTION

TO THE COURT, ALL INTERESTED PARTIES AND THEIR ATTORNEYS OF RECORD:

PLEASE TAKE NOTICE THAT on August 17, 2015, at 10:00 a.m., or as soon thereafter as the matter may be heard, in Courtroom 2 of the United States District Courthouse, 450 Golden Gate Avenue, San Francisco, California, before the Honorable Thelton E. Henderson, Defendants General Mills, Inc. and General Mills Sales, Inc. ("General Mills") will, and hereby do, move this Court for an order dismissing, or in the alternative staying, this action. This Motion is made under the prudential doctrine of primary jurisdiction, in light of recent action taken by, and petitions submitted to, the U.S. Food and Drug Administration ("FDA") involving issues directly relevant to those presented in this litigation.

This Motion is based upon this Notice, the accompanying Memorandum of Points and Authorities, the Declaration of Charles Sipos, any reply memorandum, the filings in this action, and such other matters as may be presented at or before the hearing.

DATED: July 13, 2015

Respectfully,

PERKINS COIE LLP

By: */s/ Charles Sipos*
CHARLES C. SIPOS

Attorneys for Defendants
GENERAL MILLS, INC. and GENERAL MILLS SALES, INC.

MEMORANDUM OF POINTS AND AUTHORITIES

INTRODUCTION

On June 17, 2015, the United States' Food and Drug Administration ("FDA") issued a Declaratory Order ("Order") that opened administrative proceedings to establish regulations addressing the same issue embraced by this lawsuit: At what levels, and for which products, will foods continue to lawfully contain partially hydrogenated oils ("PHOs")? Plaintiff Troy Backus wants to do an end run around those proceedings in favor of piecemeal litigation that necessarily disregards the FDA's authority and expertise. Moving forward with his lawsuit now creates an unnecessary risk of conflict between this Court's rulings and regulatory action by the FDA on matters entrusted to the agency by Congress. Accordingly, the primary jurisdiction doctrine dictates that this Court should either stay Backus' Complaint or dismiss it, so the FDA can exercise its decision-making responsibilities in the first instance for the ongoing use of PHOs.

Federal law has permitted the use of PHOs for decades, based on their status as "Generally Recognized as Safe" (GRAS). The FDA's June 17 Order finalized a previous tentative decision to revoke the GRAS status of PHOs, but established a three-year compliance period and declared that products containing PHOs may still be lawfully sold until June 18, 2018. 80 Fed. Reg. 34650 (June 17, 2015). The FDA also invited submission of "food additive petitions" during this three-year period. The purpose of these petitions is to submit evidence to the FDA to "establish, by regulation, safe conditions of use of PHOs." *See* 80 Fed. Reg. 34650 at 34657. So, PHOs are lawful for at least the next three years. And during that time, the FDA will evaluate food additive petitions to regulate the use of PHOs going forward.

Congress has granted the FDA authority to consider food additive petitions and issue accompanying regulations for PHO use. The FDA has the necessary scientific expertise to evaluate these petitions. And the Order makes clear that ongoing use of PHOs is squarely before the FDA in administrative proceedings the agency has invited. The Court should stay or dismiss this action under primary jurisdiction and allow the FDA to implement a uniform regulatory scheme for PHOs. This will avoid inconsistent results otherwise posed by case-by-case adjudications or variance between this Court's rulings and any later-announced regulations.

BACKGROUND

A. Plaintiff Backus Alleges it is Unlawful to Use PHOs in Food.

General Mills is one of the oldest and largest food manufacturers in the United States. The company makes several different varieties of baking mixes, some of which contain PHOs. Plaintiff Backus alleges he purchased and consumed General Mills baking mixes containing PHOs. *See* Compl. ¶¶4-5. Beyond that, Backus' Complaint is purposefully vague. Incredibly, he has refused to even identify the particular General Mills' products he allegedly bought or ate. What Backus has said, however, is that the General Mills' products he purchased were accurately labeled and fully disclosed the presence of PHOs. *See* Opp. to Motion to Dismiss (Dkt. 12) at 11, 15. Thus, he does not allege any misrepresentation by General Mills about its products.

Instead, Plaintiff's "sole issue with these [unidentified] products" is that they contain PHOs. *Id*. at 11. Backus alleges that PHOs were not GRAS as of the filing of his Complaint (contrary to the FDA's findings), and that PHOs contribute to negative health effects. *See* Compl. ¶¶15-21, 29-60, 73-76. Plaintiff contends it was therefore "unfair" and "unlawful" to produce food products containing any PHOs whatsoever. *Id.* ¶¶67-76, 92-98, 113-23. In other words, Backus believes General Mills violated the law simply by manufacturing varieties of the Baking Mixes containing a lawful—but in his view unsafe—food ingredient.

Based on these allegations, Backus asserts four causes of action. He alleges two causes of action under California's Unfair Competition Law (UCL), invoking the statute's "unfair" and "unlawful" prongs. *Id.* ¶¶92-98; *id.* ¶¶113-23. Relying on the same alleged harms associated with PHOs that support his other causes of action, Backus also asserts claims for public nuisance and breach of the implied warranty of merchantability. *Id.* ¶¶99-106, 107-12. On June 1, 2015, General Mills filed a motion dismiss the Complaint under Rules 12(b)(1) and 12(b)(6).[1]

This case is one of several lawsuits filed in recent months by Plaintiff's counsel Mr. Weston, all directed at either the alleged unlawfulness of PHOs, labeling for PHOs, or both.

[1] For reasons explained in General Mills' pending Motion to Dismiss, Backus alleges no credible injury—no physical harm, no economic damage—stemming from consumption of products containing PHOs. *See* Motion to Dismiss (Dkt. 8) at 7-10. So, dismissal of the Complaint on the merits would be just as proper as a dismissal or stay under primary jurisdiction.

See, e.g., Red v. General Mills, Case No. 15-cv-2232-ODW (C.D. Cal.) (the "*Red* Action"); *Backus v. Nestle*, Case No. 15-cv-1963-MMC (N.D. Cal); *McGee v. Diamond Foods*, Case No. 14-cv-02446-JAH (S.D. Cal.). In the *Red* Action, the Court issued a *sua sponte* order (Dkt. 29) requesting briefing on the primary jurisdiction doctrine, addressing whether the *Red* Action "should be dismissed" under that doctrine. Argument on that issue and General Mills' Rule 12 motion to dismiss is scheduled for July 20.

B. Congress Has Vested the FDA With Authority to Regulate PHOs Through Food Additive Petitions.

In 1938, Congress enacted the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq*., establishing a federal regulatory structure for food law overseen by the FDA. The language of the FDCA evidences Congress' intent to make the FDA arbiter of food and food ingredient issues. The FDCA empowers the FDA to convene administrative proceedings to promulgate regulations for food ingredients. *See* 21 U.S.C. § 393(b). More specifically, the FDCA authorizes the FDA to review "food additive petitions," and to promulgate regulations based on those petitions to govern the use of certain ingredients in food. *See* 21 U.S.C. § 348(c)(1)(A), 21 C.F.R. § 171.100 (describing FDA's authority to review food additive petitions and establish regulations prescribing "the conditions under which such additive may be safely used"); *see also* 80 Fed. Reg. 34650 at 34656.[2]

On June 17, the FDA issued a Declaratory Order invoking this authority to regulate PHOs via the food additive petition process, in conjunction with a decision to affirm PHO's lawful status as a food ingredient for at least the next three years. *See* 80 Fed. Reg. 34650 at 34651 & 34657.

Prior to the June 17 Order, the FDA had permitted the use of PHOs and considered them GRAS for decades based on their consistent and common usage. *See* 78 Fed. Reg. 67169 at

[2] Further evidencing an intent to defer to the FDA on food regulatory issues is Congress' decision ***not*** to provide a private right of action under the FDCA. Federal regulatory bodies, not the courts, enforce the FDCA and its implementing regulations. *See* 21 U.S.C. § 337; *see also Merrell Dow Pharm., Inc. v. Thompson*, 478 U.S. 804, 805, 810 (1986) (noting that Congress intended that "there not be a private right of action for violations" of the FDCA).

67170-71 (Nov. 8, 2013); *see also* 21 C.F.R. § 170.30(a), (c) (2015) (allowing for food ingredients to obtain GRAS status through "common use in food prior to January 1, 1958"). In November 2013, the FDA issued a determination acknowledging that federal law has permitted use of PHOs for decades based on their common usage, but which tentatively decided to revoke the GRAS status of PHOs. *See* 78 Fed. Reg. 67169 at 67170-71.

The June 17 Order—issued while General Mills' Rule 12 motion was pending—finalized this previous tentative determination. *See* 80 Fed. Reg. 34650. The FDA's Order reiterated the long history of PHO usage and its GRAS status, and declared that products containing PHOs may continue to be lawfully sold for a three-year period until June 18, 2018. *See id*. at 34650 ("Dates: Compliance date: Affected persons must comply no later than June 18, 2018."); *id.* at 34651 & 34657 (acknowledging that PHOs GRAS status). The FDA established this 3-year compliance period to allow food producers to, among other things, "exhaust existing product inventories." *Id*. at 34668-69.

During this three-year compliance period the FDA also expressly invited submission of food additive petitions to allow PHOs continued use if granted: "We encourage industry to submit food additive petitions under section 409 of the [Food, Drug, and Cosmetic] Act if industry believes that it is possible to establish, by regulation, safe conditions of use of PHOs." *Id.* at 34657. The FDA noted that one of the other reasons for setting the June 18, 2018, compliance date was "to allow time for such petitions and their review." *Id*. at 34653; *see also* Declaration of Charles Sipos ("Sipos Decl.") Ex. 1 (FDA News Release, *The FDA takes step to remove artificial trans fat in processed food* (June 16, 2015) ("The FDA has set a compliance period [in its Order] of three years. This will allow companies to either reformulate products without PHOs and/or petition the FDA to permit specific uses of PHOs.")). As explained below, food additive petitions are technical documents that the FDA has both the authority and expertise to review, and to then issue relevant regulations for PHOs as appropriate.

C. Food Additive Petitions Are Technical Documents Evaluated by the FDA, and Food Additive Petitions For PHOs are Forthcoming.

A food ingredient that does not have GRAS status can still be lawfully used as a "food additive," based on an approved food additive petition that prescribes the conditions for use of that ingredient, and an accompanying regulation establishing that use. *See* 21 U.S.C. § 348(b). Food additive petitions are complex technical documents, submitted to and evaluated by the FDA. *Id.*; *see also* 21 C.F.R.§ 171.100 (allowing the FDA to issue a regulation based on evaluation of a food additive petition). Among the technical data required for inclusion in a food additive petition are: (1) all pertinent chemical and compositional data regarding the additive;: (2) data regarding the proposed usage level of the additive; (3) data regarding the additive's physical or technical effect in the food; and (4) full reports of investigations regarding safety of the food additive. *See generally* 21 C.F.R. § 171.1(c) (listing required food additive petition data).

The FDA reviews and approves food additive petitions. *Id.* And as for food additive petitions for PHOs specifically, the FDA noted when releasing its Order that it will use its authority and expertise to evaluate such petitions during the compliance period:

> This will allow for an orderly process as companies make the transition—to reformulate products and if they choose, to *allow companies and other interested parties to use the food additive petition process* to present evidence to the FDA as to whether any uses of PHOs meet our standard of safety. Thus, industry is responsible for providing evidence to FDA to demonstrate safety, *while FDA is responsible for evaluating that evidence to determine whether to approve PHOs for any specific intended use*.

See Sipos Decl. Ex. 2 (FDA Voice, Mayne, Susan, Dir. FDA Center for Food Safety and Applied Nutrition) (Jun. 15, 2015) (emphasis added); *see also* 80 Fed. Reg. at 34656 ("[FDA has] explicit statutory authority to review, approve, and deny food additive petitions.").

Industry has already responded to the FDA's invitation to submit food additive petitions during the three-year compliance period. For example, the Grocery Manufacturers' Association ("GMA"), a trade organization representing the manufactured food industry, announced that it would be filing a petition seeking approval of PHOs as a lawful food additive and "show[ing] that the presence of trans fat from the proposed low-level uses of partially hydrogenated oils (PHOs)

is as safe as the naturally occurring trans fat present in the normal diet." *See* Sipos Decl. Ex. 3 (News Release, Grocery Manufacturers Association, GMA Statement: FDA Action on PHOs Provides Needed Transition Time for Food Manufacturers (June 16, 2015), http://www.gmaonline.org/news-events/newsroom/gma-statement-fda-action-on-phos-provides-needed-transition-time-for-food-m/). Once accepted for review, the FDA will consider this petition—along with any others submitted—in order to establish regulations for the ongoing use of PHOs after the June 18, 2018, compliance date runs. 80 Fed. Reg. at 34657 ("We are establishing a compliance date of June 18, 2018 for this order to allow time for submission of such [food additive] petitions and their review and approval, if applicable requirements are met.").

ARGUMENT

I. The Court Should Dismiss Or Stay This Action Pending The FDA's Resolution Of Food Additive Petitions For PHOs.

A. The Primary Jurisdiction Doctrine Calls for Dismissal or Stay of Actions that Implicate the Regulatory Authority of Federal Agencies.

The primary jurisdiction doctrine applies where, as here, a plaintiff's claims implicate a federal agency's expertise for a regulated product. *United States v. W. Pac. R.R. Co.*, 352 U.S. 59, 64 (1956). Primary jurisdiction permits courts to dismiss or stay an action pending resolution "of an issue within the special competence of an administrative agency." *Clark v. Time Warner Cable*, 523 F.3d 1110, 1114 (9th Cir. 2008). "[C]ourts may, under appropriate circumstances, determine that the initial decision-making responsibility should be performed by the relevant agency rather than the courts.'" *Davel Commc'ns, Inc. v. Qwest Corp.*, 460 F.3d 1075, 1086 (9th Cir. 2006) (citing *Syntek Semiconductor Co., Ltd., v. Microchip Tech. Corp.*, 307 F.3d 775, 780 (9th Cir. 2002)).

While there is no "fixed formula" for applying the doctrine of primary jurisdiction, the Ninth Circuit traditionally considers four factors: "(1) the need to resolve an issue that (2) has been placed by Congress within the jurisdiction of an administrative body having regulatory authority (3) pursuant to a statute that subjects an industry or activity to a comprehensive regulatory authority that (4) requires expertise or uniformity in administration." *Syntek*, 307 F.3d

at 781. Efficiency is the "deciding factor" in whether to invoke primary jurisdiction. *Rhoades v. Avon Prods., Inc.*, 504 F.3d 1151, 1165 (9th Cir.2007). Once a district court determines that primary jurisdiction is appropriate, it may either stay proceedings or dismiss the case without prejudice. *Astiana v. Hain Celestial Grp., Inc.*, 783 F.3d 753, 761 (9th Cir. 2015).

B. The Court Should Dismiss or Stay Backus' Complaint Under Primary Jurisdiction Doctrine.

All of the *Syntek* factors governing application of primary jurisdiction doctrine strongly favor the dismissal or stay of Backus' Complaint.

First, Plaintiff's claims require this Court to resolve an issue squarely within the purview of the FDA: Whether the inclusion of certain additives—PHOs—in food products (in particular, the Baking Mixes) is unlawful or makes the food unfit for human consumption. *See, e.g.*, Compl. ¶¶73-76, 104, 109, 116-18. The FDA's November 2013 tentative determination and June 17 Order evidence the agency's active role in considering these very issues. *See* 78 Fed. Reg. 67169-01 at 67170-71. Plaintiff himself has relied on the FDA's activities in these areas to draw support for his claims. *See* Plaintiff's Opposition to Motion to Dismiss at 4-5 (Dkt. No. 12) (invoking FDA proceedings regarding PHO GRAS status).

Second, the permissibility of food additives such as PHOs is an issue that Congress has "placed within the [primary] jurisdiction of the FDA." *Syntek*, 307 F.3d at 781; 21 C.F.R. § 10.25(b) ("FDA has *primary jurisdiction* to make the initial determination on issues within its statutory mandate.") (emphasis added); 21 U.S.C. § 348 (addressing food additives). Indeed, as to food additive petitions addressing PHOs specifically, the FDA has noted that it "is responsible for evaluating that evidence to determine whether to approve PHOs for any specific intended use." Sipos Decl. Ex. 2.

Third, food additives are indisputably subject to comprehensive regulatory authority by the FDA. *See, e.g.*, 21 U.S.C.§ 321(s) (defining the term "food additive"; exempting substance that is "Generally Recognized As Safe" from that definition); 21 U.S.C. § 348(a) (requiring premarket approval of food additives by FDA); 21 U.S.C. § 348(c) (authorizing FDA to review

food additive petitions); 80 Fed. Reg. at 34656 ("[FDA has] explicit statutory authority to review, approve, and deny food additive petitions.") .

Finally, the FDA's evaluation of PHOs' safe use as food additives is an issue that requires the agency's expertise and consistent administration of the federal regulatory scheme governing food ingredients. *Cf. Fraker v. KFC Corp.*, No. 06-1284, 2007 WL 1296571, at *4 (S.D. Cal. Apr. 30, 2007) ("To overlay the state law tort system over the FDCA would significantly increase the burdens on the FDA to ensure uniform enforcement of its administrative duties."). Food additive petitions are technical documents with complex data regarding PHO composition, technical function, and safety. 21 C.F.R.§ 171.1(c). The FDA has the authority and expertise to consider that data and, unlike this Court, the agency can issue resulting regulations establishing certain and specific levels and conditions for PHO usage. *Id.*; 21 U.S.C. § 348(b); 21 C.F.R. § 171.100. Until the FDA has evaluated those petitions, any ruling in this action is necessarily premature and potentially at odds with what the FDA may do later on a regulatory basis. So, staying or dismissing this action will avoid the real risk that any decision that the Court renders here will conflict with the FDA.

More generally, deference to the FDA allows for a uniform and national approach—via binding federal regulations—to the issue. This is far superior to the arbitrary regime created by case-by-case adjudications producing differing and potentially inconsistent outcomes. *Cf. Weinberger v. Bentex Pharms, Inc.*, 412 U.S. 645, 654 (1973) ("[U]niformity and consistency in the regulation of business entrusted to a particular agency are secured, and the limited functions of review by the judiciary are more rationally exercised, by preliminary resort for ascertaining and interpreting the circumstances underlying legal issues to agencies that are better equipped than courts by specialization, by insight gained through experience, and by more flexible procedure."). That concern is particularly acute here, as Plaintiff's counsel has peppered the federal docket with multiple complaints regarding PHO usage.[3]

[3] And at least one other court is currently considering the implications of primary jurisdiction on challenges to the use of PHOs, in a case filed by Plaintiff's counsel that is substantively indistinguishable from the instant action. *Red v. General Mills*, Case No. 15-cv-2232-ODW

Taradejna v. General Mills, Inc., 909 F. Supp. 2d. 1128 (D. Minn. 2012), is particularly instructive. The "underlying issue" in that case was "whether [milk concentrate protein] is a proper, permitted ingredient in yogurt." *Id.* at 1134. The court dismissed the case on primary jurisdiction grounds, finding that "[t]he resolution of this question falls squarely within the competence and expertise of the FDA, pursuant to the authority granted to the Agency by Congress." *Id.* at 1134-35. The same result is required here.

Suits like this one over food ingredients cannot be divorced from the FDA's regulatory system for food additives because, otherwise, the possibility of numerous suits across the country would "create[] the potential for inconsistent judicial rulings." *Id.* at 1135. There can be no uniform national regulatory program if courts decide on case-by-case basis whether it is unlawful to sell products containing PHOs, with the FDA is simultaneously resolving that same question on a national basis: "The FDA in the best position to resolve any ambiguity about the [safety of PHOs]—a matter requiring scientific and nutritional expertise." *Id.*

Moreover, whether the FDA will exercise its authority to evaluate the safe use of PHOs is not merely hypothetical—it is certain. The FDA expressly invited industry "to submit food additive petitions . . . if industry believes that it is possible to establish, by regulation, safe conditions of use of PHOs," and confirmed that the three-year compliance period was implemented to consider and resolve these petitions. 80 Fed. Reg. 34650 at 34653, 34657. The GMA intends to submit such a petition, which seeks the agency's determination that PHOs may be safely added to various food products. The FDA's resolution of this petition, and any other, therefore will necessarily reach key issues in this case.

Under these circumstances, where the central issues of this case are squarely before the FDA, and the FDA will actively resolve them (as it is statutorily required to do), the Court should defer to the agency. *See, e.g., Gitson v. Trader Joe's Co.*, 63 F. Supp. 3d 1114, 1117 (N.D. Cal. 2014) ("Because the FDA appears to be actively considering the lawfulness of the use of the term 'evaporated cane juice' on food labels, it makes sense to stay the plaintiffs' evaporated cane juice

---

(C.D. Cal.) (Dkt. 29, *sua sponte* order requesting briefing on whether action should be dismissed based on primary jurisdiction doctrine).

claims to see if the agency does, in fact, issue final guidance on the issue."); *Saubers v. Kashi Co.*, 39 F. Supp. 3d 1108, 1112 (S.D. Cal. 2014) (dismissing case on primary jurisdiction grounds because FDA is considering the propriety of using the term "evaporated cane juice" to refer to sweetener); *Thomas v. Costco Wholesale Corp.*, 2014 WL 5872808, at *5 (N.D. Cal. Nov. 12, 2014) (same).[4]

The Complaint asks the Court for a judicial ban on General Mills' use of PHOs in the products at issue—an issue that is now actively before the FDA. Asking this Court to usurp the FDA's role whether any such action is appropriate here, would risk undercutting the FDA's expert judgments and authority. It is for precisely this reason that courts wisely defer to the relevant agency. For these reasons, General Mills requests that the Court dismiss this action in deference to the FDA's primary jurisdiction.

CONCLUSION

For the foregoing reasons, General Mills requests that the Court dismiss this action pending the FDA's resolution of food additive petitions concerning the use of PHOs in food.

DATED: July 13, 2015

Respectfully,

PERKINS COIE LLP

By: */s/ Charles Sipos*
CHARLES C. SIPOS

Attorneys for Defendants GENERAL MILLS, INC. and GENERAL MILLS SALES, INC.

[4] Courts in this district have routinely applied the doctrine in lawsuits where the FDA is expected to take action. *See, e.g.*, *Swearingen v Amazon Pres. Partners*, 13-CV-4402-WHO (April 13, 2015, Dkt. 57); *Figy v. Amy's Kitchen*, 13-CV-3816-SI (Mar. 17, 2015, Dkt. 82); *Swearingen v. Santa Cruz Nat.*, 13-CV-4291-SI (Mar. 10, 2015, Dkt. 52); *Swearingen v. Yucatan Foods*, 13-CV-03544-RS (Jan. 30, 2015, Dkt. 51); *Leonhart v. Nature's Path Foods*, 13-CV-492-BLF (Jan. 13, 2015, Dkt. 64); *Gitson v. Clover-Stornetta Farms*, 13-CV-1517-EDL (Dec. 4, 2014, Dkt. 67).